

MCP - 279



The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Ex parte DANIEL McTEIGUE, NARENDAR PARIKH  
DAVID W. WYNN and RAVIVAJ S. PILLAI

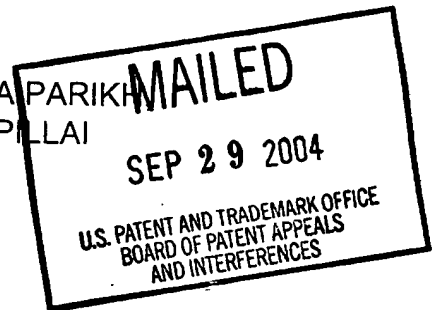
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J&J PAT. DKT. SECTION

Appeal No. 2004-1982  
Application No. 09/878,034

ON BRIEF



Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-9 and 11-24. Claim 1 is representative of the subject matter on appeal, and reads as follows:

1. A taste masked particle comprising a core containing an active ingredient and a continuous polymeric coating covering said core, said coating comprising a mixture of a) an enteric polymer; and b) a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least

70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

The examiner relies upon the following reference:

Morella et al. (Morella)                      CA 2,068,366                      May 11, 1992

Claims 1-9 and 11-24 stand rejected under 35 U.S.C. § 103(a) over Morella. After careful review of the record and consideration of the issue before us, we reverse.

#### DISCUSSION

According to the rejection, "Morella discloses a taste masked free flowing powder including microcapsules, wherein each microcapsule includes an effective amount of a core element including at least one pharmaceutically active ingredient and a substantially smooth and continuous microcapsule coating on the core element formed from a coating composition including a water-insoluble polymer." Examiner's Answer, page 3. Morella teaches further that the coating composition can further comprise an enteric polymer. See id. at 4. The rejection concludes:

Morella [ ] is deficient in the sense that the patent does not teach the particular release profile claimed by Applicant. However, it is the position of the examiner that because Morella [ ] teaches the same ingredients as Applicant, it would flow that the invention disclosed by Morella [ ] would have the same release profile as the invention claimed by Applicant. The burden is shifted to Applicant to provide evidence that the two compositions exhibit different profiles, if this is the characteristic to be relied upon to show patentable distinction. Absent such an evidence [sic], this invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Id. at 4.

The burden is on the examiner to set forth a prima facie case of obviousness. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). The examiner asserts here that the products appear to be the same because Morella teaches the same ingredients, thus the release profiles should be the same. Morella also teaches, however, that “[a]djusting the microcapsule coating composition allows modification of the release profile for the material. Controlling the process parameters including temperature, solvent concentration, spray dryer capacity, atomizing air pressure, droplet size, viscosity, total air pressure in the system and solvent system, allows the formation of a range of coats, ranging from dense, continuous, non-porous coats through to more porous microcapsule/polymer matrices.” Morella, page 15, lines 18-26. In addition, the specification teaches that “[t]he release profile of taste masked particles of the present invention can also be varied by changing the ratio of enteric and insoluble film forming polymers in the coating formulation.” Thus Morella teaches, and the instant specification supports, that one of ordinary skill in the art would not have necessarily expected the release profile of the Morella particle to be the same as the release profile of the instantly claimed invention based on the fact that they both comprise the same ingredients.

With respect to the release profile as disclosed by Morella, appellants argue, and the examiner does not appear to dispute, that Example 3 is the “closest disclosure.” Appeal Brief, page 4; see also, Examiner’s Answer, page 6.

In example 3, according to appellants, "sodium diclofenac was coated with a coating solution of ethylcellulose, hydroxypropyl methylcellulose acetate succinate and dichloromethane." Appeal Brief, page 4. The release profile as shown in Figure 3 of that reference, appellants contend, "indicates that less than 80 % of the drug had been released after 30 minutes in a pH 7.5 solution." Id.

In response, the examiner asserts

that the composition of Example 3 of the Canadian Patent provides a release profile, which indicates that less than 80% of the drug is released after 30 minutes in a pH 7.5 solution, the examiner points out that Applicant is testing his dissolution rate at pH 7.2, thus the slight difference in dissolution profiles between Applicant's invention and the invention disclosed by the prior art could be a result of the pH difference. Furthermore, it is noted that the examples in the prior art are the inventor's best mode. It is not necessary for the prior art to disclose Appellant's claimed release profile as best mode, but merely to suggest to one of ordinary skill in the art that the amounts of water-insoluble polymer and enteric polymer in the coating may be varied according to the desired rate of release of the active agent. Thus the skilled artisan would have determined the optimal concentration of the water-insoluble polymer and enteric polymer in the coating by routine experimentation, in order to achieve the desired dissolution profile of the active agent in the composition.

Examiner's Answer, page 6.


We find that Example 3 of the Morella reference does not have the dissolution profile as required by the claimed invention. As noted by appellants, the release profile as shown in Figure 3 of Morella demonstrates that less than 80% of the active agent had been released after 30 minutes in a pH 7.5 solution. In addition, we do not agree with the examiner's contention that the difference may be discounted because the claims require a pH of 7.2, whereas the pH used

by Morella to generate the release profile as shown in Figure 3 was a pH of 7.5. As can be seen from Figure 3 of Morella, as the pH is decreased from 7.5 to 1.2, the amount of active agent is decreased, rather than increased. That observation is also supported by the language in the claims, which state that "the active ingredient is at least 80% dissolved in 30 minutes at pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm." Thus, the evidence of record suggests that if the pH of the release profile of the particle of Example 3 of Morella were to be generated at a pH of 7.2, as required by the claims, rather than a pH of 7.5 as shown in Figure 3 of Morella, one of ordinary skill in the art would expect the amount of drug released to decrease, rather than increase.

Finally, the examiner asserts that "the skilled artisan would have determined the optimal concentration of the water-insoluble polymer and enteric polymer in the coating by routine experimentation, in order to achieve the desired dissolution profile of the active agent in the composition." Examiner's Answer, page 6. The examiner has not, however, pointed to any teaching or suggestion in the Morella reference, nor provided any evidence or argument, to demonstrate why the ordinary artisan would have been motivated to modify the particle having the dissolution profile shown Figure 3 of Morella to obtain a particle having the claimed dissolution profile. "[C]onclusory statements" as to teaching, suggestion or motivation to arrive at the claimed invention "do not adequately address the

issue of obviousness." In re Lee, 277 F.3d 1338, 1343-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002). Thus, we find that the examiner has failed to meet the burden of establishing a prima facie case that one of ordinary skill in the art would have been motivated to modify the particle of Morella to arrive at the claimed particle, and the rejection is reversed.

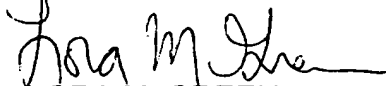
REVERSED



DONALD E. ADAMS  
Administrative Patent Judge



ERIC GRIMES  
Administrative Patent Judge



LORA M. GREEN  
Administrative Patent Judge

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